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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,985	07/15/2003	Thomas David Starkey	N9464-ICW	3040
23456	7590	02/03/2005	EXAMINER	
WADDEY & PATTERSON			SNOW, BRUCE EDWARD	
414 UNION STREET, SUITE 2020				
BANK OF AMERICA PLAZA			ART UNIT	PAPER NUMBER
NASHVILLE, TN 37219			3738	

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/619,985	STARKEY, THOMAS DAVID
	Examiner Bruce E Snow	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 November 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5, 8-11,14-16,18-21 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 32-34 is/are allowed.
- 6) Claim(s) 1,5,8-11,14-16,18-21 and 29-31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. <u>01272005</u>
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Allowable Subject Matter

Claims 32-34 are allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 9-11, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Noon et al (4,731,076).

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Noon et al teaches an apparatus fully capable of being inserted into a ventricle of a heart for limiting volume including:

- a. a hollow plastic sac 10 or 12 with two openings 14, 16 or 18, 20 (include valves)
- b. said sac being soft and compliant so that it will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed.

Claims 1, 5, 8-11, 14-16, 18-21, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Corral (5,139,517).

Corral et al teaches an apparatus for insertion into a ventricle of a heart and limits volume including:

- a. a hollow plastic sac 46 with two openings
- b. said sac being soft and compliant so that it will easily fill with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed. Said apparatus is inserted into a ventricle and the opening are connected to the annulus of the inflow and outflow valves.

Regarding claim 14, the apparatus removes the pumping pressure from the heart wall reducing stress thereon.

Regarding the limitation "an addition to a conventional operation", which could include exploratory procedures which are inherently done.

Claims 9-11, 18-21, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al (2002/0169360).

Referring to at least 12A-14C, Taylor et al teaches a flexible sac 113, 139 for placement in a ventricle of a heart, said sac having a capacity for receiving a predetermined volume of blood, and said sac, when filled to capacity, appears generally in size and shape to match the size and shape of a ventricle of an undiseased human heart. The sac allows the heart to pump in a more normal fashion reducing stress on the heart wall.

Regarding at least claims 18-19, see all embodiments taught by Taylor et al.

Regarding the limitation "an addition to a conventional operation", which could include exploratory procedures which are inherently done.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corral (5,139,517).

Corral teaches the apparatus as described the grounds of rejection above, however, is unclear if an outflow valve is used. It would have been obvious to one

having ordinary skill in the art to have utilized an outflow valve in combination with said apparatus if the natural valve was damaged or deemed unsatisfactory by the surgeon. Regarding claim 31, Corral teaches the apparatus can be used when "*the natural heart may become incapable of maintaining adequate circulation because of various disease processes, including myocardial infarction.*" It is well known in the art that this teaching includes left ventricular aneurysm. Regarding the limitation "an addition to a conventional operation", which could include exploratory procedures which are inherently done.

Response to Arguments

Applicant's arguments filed 11/22/04 have been fully considered. Regarding the rejection in view of Noon et al, applicant argues that Noon et al fails to address that the sac will fill to a predetermined volume, and when the sac has reached capacity, no further filling is allowed. For the record, the plastic sac of Noon et al has been indicated as elements 10 and 12; said elements "generally indicates" an artificial left heart and an artificial right heart and not just the interior bladder. It is within the scope of the rejection that one of the inner and outer 22 bladders or both is used in the claim interpretation.

There is absolutely no statement made by Noon et al indicating that the sacs can be filled limitlessly; the sacs must have a maximum capacity which can be interpreted as a "predetermined volume". Additionally, the sacs have been described as being flexible not elastic. The sacs of Noon et al are constructed to be flexible, made of materials such as polyurethane or silicone; applicant's device is made of the same materials. Same materials must inherently behave the same. Finally, the device of Noon et al must

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have a predetermined volume to meet the blood flow rate needed for an individual patient as determined by the surgeon.

Regarding claim 11, "the enlarged" heart does not even have to be "the heart" mentioned in the preamble of claim 10. The Examiner disagrees and truly believes a sac of Noon et al is smaller than an enlarged heart of some animal. Regarding claim 20, a sac of Noon et al is fully capable of being inserted into a chamber of a heart of some animal. This claims is merely functional language and has no structural limitations. The Examiner further believes that a sandwich bag or sac can be inserted into a chamber of heart in any orientation and the volume of the plastic from which it is constructed would reduce or limit the volume of blood into said chamber.

Regarding the rejection in view of Corral, applicant argues that it is the outer shell that limits filling to a predetermined volume and not the sac itself. Corral describes sac 46 as "a multi-layered flexible sheet of plastic material." A flexible sac does not mean it is elastic. It must have been manufactured to a predetermined volume; Corral makes no statement that any size or volume would work. Applicant is reminded of their use of the transitional phrase "including" (or similar thereto) wherein the body of the claim can comprise additional structures. Additionally, see the arguments to Noon et al which also apply here.

Regarding claim 9, Corral teaches the outer casing approximates the heart's normal diastolic ventricular dimensions (2:42 et seq.). Therefore, the Examiner strongly believes that sac 46 would have a corresponding shape and would be considered to

"appear generally in size... heart". If the sac did not correspond in shape, excess material not conforming would produce folds which would in turn produce blood clots.

Regarding method claims 14-16, 18-19, etc. Corral teaches the only claimed step of inserting into a chamber of the heart and fulfills this limitation, the preamble is given no weight giving no life to the body of the claim. On the other hand, the device of Corral takes over pumping and the heart can rest. A resting heart has less stress on the chamber walls and further enlargement will not occur.

Regarding the Taylor rejection, applicant arguments regarding claims 10-11 are not commensurate with the scope of the claims. Regarding claim 9, the device is fully capable of receiving blood and generally appears in size and shape of a ventricle of at least an infant or child. See at least figure 12B.

Regarding claims 9-11, 18-21, and 30-31, the Examiner notes that the device of Taylor is similar/the same of applicant's non-elected device shown in applicant's figure 3 which occupies ventricular volume improving heart efficiency and allowing the heart to pump a more normal volume reducing stress thereon.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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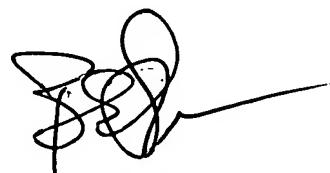
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER